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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,819	08/08/2002	John Hughes	A0000005/1-01-MG	5592

7590 06/02/2006

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EXAMINER	
SHAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,819	HUGHES ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-17 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-8 and 19-21* is/are allowed.

6)☒ Claim(s) *10-17, 22-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on March 17, 2006 has been filed. Claims 1-8, 10-17, 19-23 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-17, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horwell US Patent 5,594,022 in view of Byrans et al, (Medicinal Research Reviews, Vol 19, No. 2, 1999, pages 149-177).

Horwell et al teaches the use of NK1 receptor antagonists for treating pain. (col 2, 8, and 105-106) Horwell also teaches the compound 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]- carbamic acid benzofuran-2-ylmethyl ester [R-R*,S*)] as an NK1 antagonist (see column 2, line 6, column 8, lines 12-14 and Example 66).

Bryans et al teach the claimed instantly employed GABA analog compounds useful for treating pain. (see pages 163-165).

Both medicaments are taught as useful for treating chronic pain, and neurogenic and neuropathic pain (see claims 42-43).

It is generally considered Prima facie obvious to combine two compounds each of which is taught by the prior ad to be useful for the same purpose, in order to form a Composition which is to be used for the very same purpose. The idea for combining

them flows logically from their having been used individually in the prior art. see *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the NK 1 antagonist described in example 66 of Horwell with gabapentin of Byrans to formulate a combination drug, because they have both been used for the same purpose. Further, it would have been obvious to one of ordinary skill in the art at the time of invention to further optimize the dosages of such individual compounds and use them to improve the clinical outcome for such pains as neuropathic pain.

Claims 10-17, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Field et al (JPET 1998, 285:1226-1232) ("Field I") in view of Field et al (PAIN 1999, 80:391-398) ("Field II").

Field I describes the use of NK 1 receptor, compound 2-(1H-indol-3-yl)-1-methyl-1-(1-phenyl-ethylcarbamoyl)-ethyl]- carbamic acid benzofuran-2-ylmethyl ester [R-R*,S*)], in animal models for neutopatic pain. (see abstract, page 1229-1231).

Field II describes the use of gabapentin and pregablain in animal models of nueropathic pain. (see abstract, pages 394-397).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the NK 1 recpeor of Field I with the gabapentin or pregablin of Field II to formulate a combination formulation for treatment of neuropathic pain. It would have been further obvious to one of ordinary skill in the art at the time of invention to optimize the dosing and concentration of individual drugs by routine experimentation.

Response to Arguments

Applicant's arguments filed on March 17, 2006 have been fully considered but they are not persuasive.

Applicant argues that the cited references do not recite the synergistic effective amounts of the NK1 receptor antagonist and the GABA analogs. (see Remarks at page 6).

In response, Examiner states that Applicant's arguments are not commensurate with the scope of the rejected claims, because the rejected claims are merely directed to synergistic amounts without pointing out what such amounts are or what clinical endpoint is the effective amount for. Applicant acquiesces that one of ordinary skill in the art in possession of the cited references would have merely expected an additive effect when using the agents in combination (see Remarks at page 6, line 18). Accordingly for any clinical endpoint, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the drug amounts to the most useful combination and further avoid any potential toxicity, overdose, or excess amount. Such optimization would have also included any synergistic amount encompassed in the rejected claims. Thus, absent a showing that what range of amounts for each drug would have provided unexpected results the rejection is maintained.

Here, Applicant's arguments merely amount to a general allegation that the synergistic effective amounts for each employed compounds is somehow different from those that one of ordinary skill in the art would have been able to optimize. Examiner thus maintains the rejection because the claims do not specifically pointing out how said

limitation of the claims is patentable over the general ranges described in the art or such ranges that can be modified through optimization.

Allowable Subject Matter

Claims 1-8, 19-21 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ss

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER